## Remarks

Claims 20, 21, 24, 28, 29, 48-49, and 51-56 are currently pending in the captioned application, including independent claims 20 and 48. For instance, independent claim 20 is directed to an implantable fixed tissue that includes cross-linked elastin. More specifically, the cross-linked elastin of the implantable fixed tissue is cross-linked with a phenolic tannin cross-linking agent. The implantable fixed tissue is a high-elastin content tissue, with an elastin content of at least about 30% by weight of the implantable fixed tissue. In addition, the implantable fixed tissue is an implantable valve leaflet.

Support for the presently presented amendments can be found throughout the application as filed, for instance at page 7, paragraphs [0033]-[0034].

In the Final Office Action, independent claims 20 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tasiaux, et al. (International Publication No. WO 01/21228) in view of Nguyen-Thien-Nhon (U.S. Patent No. 6,001,126).

Tasiaux, et al. discloses cardiac valves made from a biological or biocompatible tissue having a resistance to calcification. Specifically, an appropriate biological tissue may be a tissue removed from the heart of an animal, from the aortic valve of an animal, or from the pericardium of an animal (p. 2, ll. 25-28). These tissues, however, are not high elastin content tissues as are found in the pending claims. As discussed in the captioned application (see, e.g., paragraphs [0050], [0053], and Figure 4), pericardial tissue contains only about 2% by weight elastin, and aortic cusps (tissue of the aortic valve) contain less than 10% elastin.

In the Final Office Action, it was asserted that Tasiaux, et al. teach treating all cardiac tissue and vessels. Applicants respectfully disagree, as Applicants find no reference in Tasiaux, et al. to the treatment of cardiac vessels. Tasiaux, et al. limits their source tissue to heart tissue, aortic valve tissue, and pericardium tissue, with no suggestion for the utilization of high elastin content tissue as is found in the pending claims.

In contrast, the fixed implantable tissue of the pending claims include an elastin content of at least about 30% by weight. Thus, Tasiaux, et al. fails to disclose limitations of pending independent claims 20 and 48, and specifically, Tasiaux, et al.

fails to disclose an implantable fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue.

As such, Tasiaux, et al. was combined with Nguyen-Thien-Nhon in an attempt to render the claims obvious. However, Nguyen-Thien-Nhon also fails to disclose or suggest an implantable fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue.

The implantable fixed tissue of Nguyen-Thien-Nhon is a stentless heart valve. This implantable fixed tissue is formed of a preserved segment of mammalian aorta that includes an inflow rim or inflow end IE, an outflow rim or outflow end OE, the aortic valve leaflets therewithin, and segments of the right and left main coronary arteries extending from the aortic segment (col. 4, ll. 18-27). At least portions of this implantable fixed tissue, for instance the aortic valve leaflets within the aortic segment, are extremely low in elastin content. Accordingly, the implantable fixed tissue *as a whole* cannot be assumed to have a high elastin content as is found in the implantable fixed tissues of the pending claims.

A reference must be read *as a whole*. According to Nguyen-Thien-Nhon, the implantable fixed tissue is *the entire preserved segment* as described. Thus, even if the references were combined as suggested in the Office Action, the resulting fixed tissue would include the segment of Nguyen-Thien-Nhon, which includes all of an inflow rim or inflow end IE, an outflow rim or outflow end OE, the aortic valve leaflets therewithin, and segments of the right and left main coronary arteries extending from the aortic segment, and this segment could be treated according to the teachings of Tasiaux, et al.

This treated segment, i.e., this implantable fixed tissue, includes multiple different portions, each of which have different protein characteristics. At least some portions of this implantable fixed tissue (e.g., the aortic valve leaflets) have an extremely low elastin content. No evidence has been provided to suggest that this implantable segment includes an elastin content of at least about 30% by weight of the implantable fixed tissue, as is found in independent claims 20 and 48. This implantable fixed tissue includes portions with extremely low elastin content, and as a result, it cannot be assumed that the segment meets the limitations of the claims. Inherency

may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. To establish inherency, the evidence must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. The mere fact that a certain thing *may* occur or be present in the reference is not sufficient. Simply stated, inherency may not be established by probabilities or possibilities. The possibility that certain specific portions of the implant of Nguyen-Thien-Nhon may have a high elastin content, does not therefore lead to the conclusion that the entire implantable tissue contains an elastin content of greater than 30%, as is required in independent claims 20 and 48.

Applicants respectfully maintain that independent claims 20 and 48 patentably define over the cited references for at least the reason that even if combined as suggested, the combined references still fail to teach limitations of the claims. Neither Tasiaux, et al. nor Nguyen-Thien-Nhon disclose or suggest an implantable fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue.

Moreover, neither Tasiaux, et al. nor Nguyen-Thien-Nhon disclose or suggest an implantable fixed tissue in the form of a valve leaflet that includes an elastin content of at least about 30%, as is found in independent claim 20. While the implantable tissues of both Tasiaux, et al. and Nguyen-Thien-Nhon can include valve leaflets, these valve leaflets are not formed of a fixed tissue including an elastin content of at least about 30% of the implantable fixed tissue, as is required in independent claim 20.

In the Office Action, independent claims 20 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tasiaux, et al. in view of Nguyen-Thien-Nhon and further in view of Yang (U.S. Patent Application Publication 2003/0078659).

Yang is directed to methods for forming elongated graft elements, and specifically, prostheses for reconstruction or repair of ligaments, tendons, or other body wall deficiencies (p. 1, ¶[0009]). The tubular tissue of the graft elements is processed to form an elongated graft element that has a different orientation from the original orientation of the tubular tissue, so that the tissue can have sufficient strength and initial tension to be used as a graft for ligaments, tendons, and body wall deficiencies

(p. 2, ¶[0023]). Luminal or tubular tissues including venous tissue such as vena cava can be utilized to form the ligaments, tendons, or body wall deficiencies (p. 2, ¶[0025]).

Applicants respectfully submit that even if the references were combined as suggested, and the formation process for forming the graft elements of Yang were to include treatment methods as disclosed by Tasiaux, et al. in view of Nguyen-Thien-Nhon, the combined references would still fail to disclose or suggest elements of the pending claims. For example, the high elastin content implantable tissues of Yang can be used to form ligaments, tendons, or body wall defects, rather than the implantable valve leaflet of independent claim 20 or the vein or artery of independent claim 48.

Applicants respectfully submit that even if combined, the combined references fail to disclose or suggest an implantable tissue including an elastin content of at least about 30% that includes elastin cross-linked with a phenolic tannin cross linking agent in which the implantable fixed tissue is an implantable valve leaflet, as in independent claim 20, or is an implantable vein or artery, as in independent claim 48. Accordingly, Applicants respectfully submit that independent claims 20 and 48 patentably define over Tasiaux, et al. in view of Nguyen-Thien-Nhon and further in view of Yang, and request withdrawal of the rejection.

Applicants also respectfully submit that for at least the reasons indicated above relating to corresponding independent claims 20 and 48, the pending dependent claims patentably define over the references cited. However, Applicants also note that the patentability of the dependent claims certainly does not hinge on the patentability of independent claims. In particular, it is believed that some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

It is believed that the present application is in complete condition for allowance and favorable action is therefore requested. Examiner Khan is invited and encouraged to telephone the undersigned at her convenience should there be any questions with regard to this application.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

DORITY & MANNING, P.A.

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